DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 13 2005

Mr. Terry Langford
President & CEO
Langford IC Systems, Incorporated
310 S. Williams Boulevard, Suite 270
Tucson, Arizona 85711

Re: K043314
Trade/Device Name: Manzi Cleaner System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscopes and Accessories
Regulatory Class: II
Product Code: NVE
Dated: June 2,2005
Received: June 2,2005

Dear Mr. Langford:

This letter corrects our substantially equivalent letter of June 20,2005, regarding the Product Code.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

JUN 2 0 2005

510(k) Summary – K043314, Manzi Cleaner System

Applicant's Name, Address, Telephone, Fax, Contact Person

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Contact Person

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June 17, 2005

1.0 CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

Classification Name: Pending - Currently Undefined, Class II
Common / Usual Name: Medical Device Cleaner System
Device Classification: 21 CFR § 876.1500, Endoscope and accessories
Proprietary Name: Manzi Cleaner System

2.0 PREDICATE DEVICE

System 83 Plus™ Washer-Disinfector, K983017

3.0 INDICATIONS FOR USE

The Manzi Cleaner, when used in accordance with its labeling and the Manzi Detergent MD10, is for the cleaning of bronchoscopes in a health care setting by health care workers.

4.0 DESCRIPTION OF THE DEVICE

The Manzi Cleaner System consists of a Manzi Cleaner and a proprietary Manzi Detergent, MD10.

The Manzi Cleaner is a self-contained stand-alone system of hardware and software designed to clean bronchoscopes using the MD10 detergent and a patented push-pull agitation system. The push-pull agitation system effectively scrubs the interior and exterior surfaces of the bronchoscope without the use of special connectors. The scope is placed in a processing chamber where it is exposed to a push-pull agitation cleaning cycle followed by two hot water rinses.

The hardware for the Manzi Cleaner consists of a stainless steel processing chamber, a push-pull agitation pump, and a variety of components that are mounted in a movable covered frame. The cleaner system utilizes accessories such as disposable water filters, reusable bronchoscope trays, and printer paper.

The Manzi Cleaner is designed to: (1) be used in accordance with the reprocessing instructions provided in the operator's manual of the instruments being processed, and (2) facilitate the health care facility's compliance with reprocessing guidelines published by SGNA, APIC, AORN, ASGE, CDC, and other professional organizations.

MD10 is a low foaming anionic chemical detergent packaged in custom containers for attachment to the Manzi Cleaner. The detergent is automatically diluted to a use dilution of 2.0% detergent concentration. MD10 is intended to be used exclusively with the Manzi Cleaner.

5.0 SUMMARY OF NONCLINICAL TESTS

5.1 Qualification Testing – FDA Guidance

The Manzi Cleaner was tested and found to conform with the requirements of the current edition of **Class II Special Controls Guidance Document: Medical Washers and Medical Washer – Disinfectors; Guidance for the Medical Device Industry and FDA Review Staff, issued on February 7, 2002**. The table below identifies the qualifications performed and the results obtained:

Requirement			Results
5.	Performance Data		
	5.1	Process Parameter Physical Tests	Passed
	5.2	Simulated Use Tests	Passed
	5.3	Cleaning Efficacy	Passed
	5.4	Disinfection Efficacy	Not Applicable
	5.5	Rinsing Efficacy	Passed
	5.6	Self Disinfection Efficacy	Not Applicable
	5.7	Other Tests	Passed
	5.8	In – Use Tests	Passed
6.	Toxicological Evaluation of Residues		Passed
7.	Software Documentation		Passed
8.	Electrical Safety Documentation		Passed
9.	Electromagnetic Compatibility		Passed

5.2 Qualification Testing – EU Guidance

The Manzi Cleaner was also tested and found to conform with the requirements of the Draft prEN ISO 15883-1: 2003, Washer-disinfectors – Part 1: General Requirements, Definitions and Tests and Draft prEN ISO 15883-4: 2001, Washer-disinfectors – Part 4: Requirements and Tests for Washer-Disinfectors Employing Chemical Disinfection for Thermo-Labile Endoscopes as identified in the Table below.

prEN ISO 15883-1: 2003 Requirement		Results
6.10 Annex B	Cleaning Efficacy – Scope Ninhydrin Horse serum- prEN 15883-4 Annex B.1.1	Passed
Annex E	Cleaning Efficacy – Surrogate Ninhydrin Horse serum- prEN 15883-4 Annex B.1.1 Surrogate - prEN 15883-4	Passed

5.3 Qualification Testing – Langford IC Systems (LIC) Requirements

The Manzi Cleaner was also tested and found to conform to the LIC requirement identified in the table below.

LIC Requirement	Results
A four spore log reduction of microbial load on scopes contaminated with Birmingham soil mixture inoculated with Bacillus subtilis spores at a concentration of > 10^7 spores/ml.	Passed > 4 spore log reduction
Cleaning Efficacy: Reduction of protein loading of scopes contaminated with a Protein Laden Soil to Remaining Protein levels of < 6.4 µg/cm² (Ref: AAMI TIR30: 2003, A Compendium of Processes, Materials, Test Methods, and Acceptance Criteria for Cleaning Reusable Medical Devices.).	Passed Remaining Protein levels of < 6.4 µg/cm²

6.0 OVERALL PERFORMANCE CONCLUSIONS

The studies demonstrate that the Manzi Cleaner System is safe and effective for the cleaning of bronchoscopes within the stated indications for use for the Manzi Cleaner and the Manzi Detergent, MD10 and establishes substantial equivalence of the Manzi Cleaner System to the predicate device, the System 83 Plus™ Washer-Disinfector.

Indications for Use

510(k) Number (if known): K043314

Device Name: Manzi Cleaner System

Indications for Use: The Manzi Cleaner, when used in accordance with its labeling and the Manzi Detergent MD10, is for the cleaning of bronchoscopes in a health care setting by health care workers.

Prescription Use _____ AND/OR Over-The-Counter Use __x__
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K 043314